

§ 170.535 ONC-ACB application reconsideration.

(a) An applicant may request that the National Coordinator reconsider a denial notice only if the applicant can demonstrate that clear, factual errors were made in the review of its application and that the errors' correction could lead to the applicant obtaining ONC-ACB status.

(b) *Submission requirement.* An applicant is required to submit, within 15 days of receipt of a denial notice, a written statement to the National Coordinator contesting the decision to deny its application and explaining with sufficient documentation what factual error(s) it believes can account for the denial. If the National Coordinator does not receive the applicant's reconsideration request within the specified timeframe, its reconsideration request may be rejected.

(c) *Reconsideration request review.* If the National Coordinator receives a timely reconsideration request, the National Coordinator is permitted up to 15 days from the date of receipt to review the information submitted by the applicant and issue a decision.

(d) *Decision.*

(1) If the National Coordinator determines that clear, factual errors were made during the review of the application and that correction of the errors would remove all identified deficiencies, the applicant's authorized representative will be notified of the National Coordinator's determination and the applicant's successful achievement of ONC-ACB status.

(2) If, after reviewing an applicant's reconsideration request, the National Coordinator determines that the applicant did not identify factual errors or that the correction of the factual errors would not remove all identified deficiencies in the application, the National Coordinator may reject the applicant's reconsideration request.

(3) *Final decision.* A reconsideration decision issued by the National Coordinator is final and not subject to further review.

§ 170.540 ONC-ACB status.

(a) *Acknowledgement and publication.* The National Coordinator will acknowledge and make publicly available

the names of ONC-ACBs, including the date each was authorized and the type(s) of certification each has been authorized to perform.

(b) *Representation.* Each ONC-ACB must prominently and unambiguously identify the scope of its authorization on its Web site and in all marketing and communications statements (written and oral) pertaining to its activities under the permanent certification program.

(c) *Renewal.* An ONC-ACB is required to renew its status every three years. An ONC-ACB is required to submit a renewal request, containing any updates to the information requested in § 170.520, to the National Coordinator 60 days prior to the expiration of its status.

(d) *Expiration.* An ONC-ACB's status will expire three years from the date it was granted by the National Coordinator unless it is renewed in accordance with paragraph (c) of this section.

§ 170.545 Complete EHR certification.

(a) When certifying Complete EHRs, an ONC-ACB must certify in accordance with all applicable certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC-ACB must provide the option for a Complete EHR to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Gap certification.* An ONC-ACB may provide the option for and perform gap certification of previously certified Complete EHRs.

(d) *Inherited certified status.* An ONC-ACB must accept requests for a newer version of a previously certified Complete EHR to inherit the certified status of the previously certified Complete EHR without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified Complete EHR, an ONC-ACB must review an attestation submitted by the developer of the Complete EHR to determine whether any change in the newer version has adversely affected the Complete EHR's capabilities for which certification criteria have been adopted.

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(2) An ONC-ACB may grant certified status to a newer version of a previously certified Complete EHR if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

(e) An ONC-ACB that has been authorized to certify Complete EHRs is also authorized to certify all EHR Modules under the permanent certification program.

§ 170.550 EHR Module certification.

(a) When certifying EHR Module(s), an ONC-ACB must certify in accordance with the applicable certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC-ACB must provide the option for an EHR Module(s) to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Gap certification.* An ONC-ACB may provide the option for and perform gap certification of previously certified EHR Module(s).

(d) An ONC-ACB may provide an updated certification to a previously certified EHR Module(s).

(e) *Privacy and security certification.* EHR Module(s) shall be certified to all privacy and security certification criteria adopted by the Secretary, unless the EHR Module(s) is presented for certification in one of the following manners:

(1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

(2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC-ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion.

(f) *Inherited certified status.* An ONC-ACB must accept requests for a newer

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version of a previously certified EHR Module(s) to inherit the certified status of the previously certified EHR Module(s) without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified EHR Module(s), an ONC-ACB must review an attestation submitted by the developer(s) of the EHR Module(s) to determine whether any change in the newer version has adversely affected the EHR Module(s)' capabilities for which certification criteria have been adopted.

(2) An ONC-ACB may grant certified status to a newer version of a previously certified EHR Module(s) if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

EFFECTIVE DATE NOTE: At 77 FR 54291, Sept. 4, 2012, §170.550 was amended by revising paragraph (e), redesignating paragraph (f) as paragraph (g), and adding a new paragraph (f), effective Oct. 4, 2012. For the convenience of the user, the added and revised text is set forth as follows:

§ 170.550 EHR Module certification.

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(e) *Privacy and security certification.* For certification to the 2011 Edition EHR certification criteria, EHR Module(s) shall be certified to all privacy and security certification criteria adopted by the Secretary, unless the EHR Module(s) is presented for certification in one of the following manners:

(1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

(2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC-ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion.

(f) When certifying an EHR Module to the 2014 Edition EHR certification criteria, an ONC-ACB must certify the EHR Module in accordance with the certification criteria at:

(1) Section 170.314(g)(1) if the EHR Module has capabilities presented for certification